In Order to Achieve Commercial Success, Our Products Must Gain Market Acceptance

We manufacture and market one principal product: Apligraf. We have only recently begun to market Apligraf through Novartis and to generate revenues from the commercialization of this product. Products under development will require additional research and development efforts, including clinical testing and regulatory approval, prior to commercial use. Our potential products are subject to the risks of failure inherent in the development of medical products based on new technologies. These risks include the possibilities that:

. Our approach will not be successful;
. Our potential products will be found to be unsafe, ineffective or otherwise will fail to meet applicable regulatory standards or receive necessary regulatory clearances;

. The potential products, if safe and effective, will be difficult to develop into commercially-viable products, will be difficult to manufacture on a large scale, will be uneconomical to market, or will fail to obtain acceptance by the medical community;
. Proprietary rights of third parties will preclude us from marketing such products; or
. Third parties will market superior or equivalent products.

Our business results would be hurt if were unable to demonstrate to the medical community the efficacy, relative safety and cost effectiveness of treating patients with our products or if our products were not accepted as alternatives to other existing or new therapies.

Our Stock Price Is Volatile

The biotechnology sector seems particularly vulnerable to abrupt changes in investor sentiment. Stock prices of companies in the biotechnology industry, including ours, can swing dramatically, with little relationship to operating performance. Our stock price may be affected by a number of factors including, but not limited to, (1) clinical trial results and other product development events, (2) the outcome of litigation, (3) decisions relating to intellectual property rights, (4) the entrance of competitive products into our market, (5) changes in reimbursement policies or other practices related to the pharmaceutical industry or (6) other industry and market changes or trends.

COLLABORATIVE AND OTHER AGREEMENTS

In January 1996, we entered into an agreement with Novartis Pharma AG granting them exclusive global marketing rights to Apligraf. Under the agreement, Novartis is responsible for Apligraf sales and marketing costs worldwide, as well as all clinical trials, registrations and patent costs outside the US. The agreement provides us with up to $40,000,000 in equity investments, research support and milestone payments, of which $12,750,000 was received during 1998, $2,500,000 in 1997 and $11,500,000 in 1996. The remaining payments are based upon achievement of specified events. Under the agreement, we supply Novartis' global requirements for Apligraf and receive revenue consisting of a per unit manufacturing payment and royalty on product sales.

In late 1998, we entered into research collaborations with Estee Lauder Companies Inc. and with Novavax, Inc.

In 1995, we entered into a supply arrangement with Biomet, Inc. under which Biomet may, but is not obligated to, purchase collagen from us. Revenues under this agreement are included in other income.

In 1994, we signed a license agreement with Toyobo Ltd. granting Toyobo a license to manufacture and market Testskin in Japan in exchange for royalty payments. Additionally, Toyobo may, but is not obligated to, purchase collagen and other products from us. Revenues under this arrangement are included in other income.

Additionally, we entered into an agreement effective January 1999 with the University of British Columbia that grants us an exclusive, worldwide license to use and sublicense certain UBC technology and to manufacture, distribute and sell products based on that technology.

RESEARCH AGREEMENTS

The research agreements summarized below generally are funded over a one or two-year period. Each agreement is reviewed at least annually and the amounts to be funded for the next period are then determined. Either party may cancel the agreement upon advance written notice. Total payments under these agreements were $648,000, $571,000 and $438,000 for 1998, 1997 and 1996, respectively. Information regarding the date entered into, the entity that the agreement is with and the area of research or development are summarized as follows:

. April 1998, Medvet Science Pty. Ltd., stem cells;
. September 1996, Children's Hospital (Boston), graft acceptance;
. June 1996, Massachusetts General Hospital, bioartificial liver;
. December 1995, Brigham and Women's Hospital, biology of surface tissues (e.g., oral mucosa, skin appendages);
. March 1995 (contract expired without renewal in 1998), Harvard Medical School, extracellular matrix related therapeutics; and
. 1995, Hebrew University, connective tissue.

RESEARCH AND DEVELOPMENT

We plan to continue to focus product development efforts on high-quality cell therapy, connective tissue and other types of tissue-engineered products for a variety of areas, including wound care, general and reconstructive surgery, liver disease and cardiovascular medicine.

Our research and development staff consists of scientists and laboratory assistants with technical backgrounds in cell biology, matrix biology, cell culture, immunology, cryopreservation, molecular biology and clinical medicine.

For 1998, 1997 and 1996, research and development expenses were $17,542,000, $13,854,000, and $10,647,000, respectively, which include production costs and funding of the research and other agreements noted above.

EMPLOYEES

As of March 4, 1999, we had 194 full-time employees. We have established a stock option plan providing equity incentives, an employee stock purchase plan and a 401(k) plan for all full-time employees. We believe that, through equity participation, attractive fringe benefit programs and the opportunity to contribute to the development and commercialization of new products using new technology, we will continue to be able to attract highly-qualified personnel.

SCIENTIFIC ADVISORY BOARD

We have a Scientific Advisory Board composed of five physicians, professors and scientists in various fields of medicine and science. The SAB meets from time to time to advise and consult with management and our scientific staff. Each member of the SAB is expected to devote only a portion of his time to us and may have consulting or other advisory arrangements with other entities that may conflict or compete with his obligations to us. Members of the SAB have no formal duties, authority or management obligations.

ITEM 2. PROPERTIES

We lease approximately 70,000 square feet of space in Canton, Massachusetts at an annual average base rent of approximately $562,000, plus operating expenses. We occupy our current premises under a lease that expires on September 30, 2004. This lease has three options to extend the term for an additional five years each option. We have provided written notice to the landlord of our intent to lease all of the remaining space at this primary facility starting November 1, 1999. Taxes, insurance and operating expenses are our responsibility under the terms of the lease. We also have a second lease for warehouse and office space that expires on October 31, 1999. Additionally, in January 1999, we entered into a noncancelable operating lease for certain office equipment.

We plan to add a second manufacturing facility to enable further expansion. We believe that current facilities will adequately support manufacturing needs and research and development activities through the end of 1999 and beyond.

ITEM 3. LEGAL PROCEEDINGS

None

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

None

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Our common stock is traded on the American Stock Exchange under the symbol ORG. On March 4, 1999, there were 668 shareholders of record of our common stock. The table below lists the high and low quarterly range of reported closing prices of our common stock during the past two years.

	1998		1997	
	High	Low	High	Low
First Quarter	$ 27 3/16	$ 15 9/16	$ 13 7/16	$ 9 1/8
Second Quarter	35 3/16	19 5/8	12 13/16	8 15/16
Third Quarter	18 15/16	8 7/8	19 1/4	10 7/8
Fourth Quarter	16 3/8	9 3/16	24 1/16	18 3/16

The amounts above have been adjusted to reflect a one-for-four stock split accounted for as a stock dividend distributed on April 29, 1998 to stockholders of record as of April 22, 1998 and two one-for-four stock splits accounted for as stock dividends distributed on November 28, 1997 and May 2, 1997 to stockholders of record as of November 21, 1997 and April 25, 1997, respectively. All related data in the consolidated financial statements reflect this stock dividend for all periods presented, except for the Statements of Changes in Stockholders' Equity. No cash dividends have been paid to date on our common stock and we do not anticipate paying cash dividends in the foreseeable future.

ITEM 6. SELECTED FINANCIAL DATA (IN THOUSANDS, EXCEPT SHARE DATA AND NUMBER OF EMPLOYEES)

	For the Years Ended December 31,				
	1994	1995	1996	1997	1998
Revenues	$ 996	$ 627	$ 7,527	$ 3,531	$ 8,997
Net Loss	(10,441)	(12,737)	(7,499)	(19,807)	(14,031)
Net Loss Per Common Share	(0.46)	(0.52)	(0.27)	(0.70)	(0.48)
Working Capital	8,407	12,886	11,256	4,843	15,541
Capital Expenditures	463	319	3,311	1,069	2,464
Total Assets	15,127	19,304	22,436	13,780	26,710
Stockholders' Equity	13,949	17,798	18,478	11,523	23,239
Number of Employees	94	97	115	137	186

ITEM 7 MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

In Management's Discussion and Analysis, we explain the general financial condition and results of operations for Organogenesis Inc. As you read this MD&A, referring to our consolidated financial statements that follow may be helpful. Further information on the company, our lead product and our pipeline is contained in the "Business" section of this Form 10-K.

OVERVIEW OF ORGANOGENESIS INC.

Organogenesis designs, develops and manufactures medical therapeutics containing living cells and/or natural connective tissue. The company was formed to advance and apply the emerging field of tissue engineering to major medical needs. Our product development focus includes living tissue replacements, cell- based organ assist devices and other tissue-engineered products.

OUR LEAD PRODUCT, APLIGRAF

On May 22, 1998, our lead product, Apligraf living skin construct, was approved for marketing in the US. Apligraf is the only mass-manufactured product containing living human cells to be approved for marketing through the FDA PMA process. Novartis Pharmaceuticals Corporation launched Apligraf in the US in June 1998. Novartis Pharma AG has global Apligraf marketing rights and also markets Apligraf in Canada.

Novartis' marketing strategy is to first establish Apligraf as the new standard of care for venous leg ulcers. The next potential large market for Apligraf is expected to be diabetic ulcers. Patient enrollment in the Apligraf diabetic ulcer pivotal trial was completed in November 1998; we plan to submit a PMA supplement to the FDA within the next twelve months. An Apligraf study in burns has been completed; data from this study was presented in February 1999. Two studies in skin surgery have been completed and their data has been or is expected to be published. A multicenter, controlled Apligraf pivotal trial studying the cosmetic outcome of wounds due to skin cancer removal is underway. We also plan to initiate a study in pressure sores. A study is underway for epidermolysis bullosa through an investigator-sponsored investigational device exemption.

OUR PIPELINE

Our pipeline includes Vitrix soft tissue replacement product, a bioartificial liver and a vascular graft, as well as the GraftPatch and engineered collagen fibril technology out-licensing opportunities. We have an active and expanding business development program related to our products and technologies.

RESULTS OF OPERATIONS

With the approval and launch of Apligraf, we began a new era of operations. We are seeing, as expected, a gradual ramp-up in sales. We expect production costs to exceed product sales for the near term due to start-up expenses and the high costs associated with low volume production. However, we expect production volume to increase.

REVENUE

Total revenues for fiscal years 1996, 1997 and 1998 were $7,527,000, $3,531,000 and $8,997,000, respectively. These amounts consist of:

	1996	1997	1998
R&D support and milestone payments	$6,500,000	$2,500,000	$6,750,000
Product sales, royalties, and other income	$ 42,000	$ 529,000	$1,189,000
Interest income	$ 985,000	$ 502,000	$1,058,000

The year-over-year increase in product sales, royalties and other income is mainly due to sale of product to Novartis, including product to support the Canadian and US launches of Apligraf. Apligraf commercial sales for the 1998 fourth quarter increased 80% from the third quarter. We expect Apligraf commercial sales to continue to increase. Novartis expects to launch Apligraf in selected European countries in 1999. R&D support payments are recognized when earned. The year-over-year changes in interest income are primarily due to the difference in funds available for investment.

EXPENSES

Research and development expenses: Our R&D expenses consist of costs associated with research, development, clinical, quality systems and operations. R&D expenses increased to $17,542,000 for 1998 from $13,854,000 in 1997 and $10,647,000 in 1996. The increase in 1998 was primarily due to clinical trials activity, including the Apligraf diabetic ulcer pivotal trial and non-recurring expenses related to FDA approval; progressing preclinical programs, including the Vitrix soft tissue replacement product; and investing in manufacturing operations, including personnel additions. The increase in 1997 was primarily due to personnel additions, mainly in operations and clinical research; expansion of facilities, resulting in higher non-cash depreciation charges and increased occupancy costs; and other activities supporting our research and development programs, including the Apligraf diabetic ulcer pivotal trial and the engineered collagen fibrils and bioartificial liver research programs. We expect to continue to expand Apligraf manufacturing operations and to advance our pipeline during the next 12 months. The majority of our funding continues to be used for R&D and operating activities.

General and administrative expenses: Our G&A expenses include the costs of our corporate, investor/public relations, finance, information technology and human resource functions. G&A expenses increased to $5,486,000 for 1998 from $3,929,000 in 1997 and $4,379,000 in 1996. The 1998 increase is primarily due to adding support staff and higher consulting and professional services, partially relating to regulatory-related activities that are nonrecurring. The 1997 decrease was primarily due to a reduction in the use of outside services. This decrease was partially offset by an increase in personnel costs. Additionally, in May 1997, we incurred a one-time, non-cash compensation charge of $5,555,000 relating to the extension of the term of a stock option held by an officer. We continue to manage G&A expenses at a relatively steady to decreasing percent of total expenditures and expect the growth in G&A expenses to increase at a slower rate.

[CHART APPEARS HERE]

NET INCOME

We incurred a net loss of $14,031,000, or $.48 per share - basic and diluted for 1998, compared to a net loss of $19,807,000, including the $5,555,000 non-cash charge, or $.70 per share - basic and diluted for 1997 and a net loss of $7,499,000, or $.27 per share - basic and diluted for 1996. We may incur additional losses as expenditures continue to increase due to expansion of operations and research programs.

CAPITAL RESOURCES AND LIQUIDITY

FUNDS USED IN OPERATIONS

At December 31, 1998, we had cash, cash equivalents and investments in the aggregate amount of $17,841,000 and working capital of $15,541,000, compared to $6,145,000 and $4,843,000, respectively, at December 31, 1997. Cash equivalents consist of money market funds, which are highly liquid and have original maturities of less than three months. Investments consist of securities that have an A or A1 rating or better with a maximum maturity of two years. Cash used in operating activities was $11,587,000 in 1998 and $14,473,000 in 1997, primarily for financing our ongoing research, development and manufacturing operations.

CAPITAL SPENDING

Capital expenditures were $2,464,000 and $1,069,000 during 1998 and 1997, respectively, primarily related to further build-out of the current facilities to support Apligraf manufacturing and the acquisition of laboratory equipment for expanded research and development programs. We will continue to utilize funds during 1999 to expand our current facility in the areas of Apligraf manufacturing, quality systems labs and packaging. We also plan to add a second facility in the future to enable further expansion.

NOVARTIS SUPPORT

The collaborative agreement with Novartis provides us with up to $40,000,000 in equity investments, research support and milestone payments, of which $12,750,000 was received during 1998, $2,500,000 in 1997 and $11,500,000 in 1996. The remaining payments are based upon achievement of specified events. Under the agreement, we supply Novartis' global requirements for Apligraf and receive revenue consisting of a per unit manufacturing payment and royalties on product sales.

TAXES

At December 31, 1998, we had federal net operating loss and tax credit carryforwards of approximately $101,500,000 and $2,668,000, and state net operating loss and tax credit carryforwards of approximately $74,127,000 and $1,676,000. These losses and tax credits are available to reduce federal and state taxable income and income taxes, respectively, in future years, if any. However, the realizability of deferred tax assets is not assured as it depends upon future taxable income. Accordingly, we have recorded a 100% valuation allowance against these assets. We are required to recognize all or a portion of net deferred tax assets, with corresponding increases to net income, when we believe, given the weight of all available evidence, that it is more likely than not that all or a portion of the benefits of net operating loss carryforwards and other credits will be realized. However, there can be no assurance that we will ever realize any future cash flows or benefits from these losses and tax credits. Ownership changes may result in future limitations on the utilization of net operating losses and research and development tax credit carryforwards.

FINANCING

From inception, we have financed our operations substantially through private and public placements of equity securities, as well as receipt of research support and contract revenues, interest income from investments, sale of products and receipt of royalties. During 1998, financing activities provided additional cash and working capital from: the sale of 200 shares of Series C convertible preferred stock that generated net proceeds of approximately $19,117,000; equity investments totaling $6,000,000 from Novartis; and the exercise of stock options of $1,021,000, partially offset by the purchase of treasury stock totaling $391,000. The repurchased stock will provide us with treasury shares for general corporate purposes. Financing activities provided cash of approximately $7,247,000 during 1997 from the exercise of stock options and warrants.

At December 31, 1998, we had approximately 62 shares of Series C convertible preferred stock outstanding. In the event that any Series C preferred stock are outstanding on the mandatory conversion date of March 26, 2000, we have the option of redeeming any such outstanding Series C preferred stock by: (1) paying cash equal to the product of the number of Series C preferred stock outstanding multiplied by the stated value of $100,000 per share; (2) issuing common stock equal to 1.15 of the stated value divided by the average of the closing bid prices for the 20 consecutive trading days prior to the mandatory conversion date; or (3) any combination of these methods.

On March 30, 1999, we closed a financing of $15,000,000 through the private placement of five year convertible debentures and 300,000 warrants to purchase common stock. We may raise up to approximately $5,000,000 additional under this placement. The debentures are convertible at a fixed price of $15.00 per share at any time on or after March 30, 2000. Interest on the debentures accrues at 7% annually, payable in cash, common stock (at the average trading price for the twenty trading days preceding the due date) or any combination thereof, at our option, semi-annually on September 30 and March 31 or on the date any of the principal outstanding under the notes has been converted into common stock. At our option, at any time on or after March 30, 2002, the debentures may be prepaid by conversion of the principal into common stock at the conversion price of $15, cash or any combination thereof and payment of any accrued interest as described above, provided that the average per share market value for the twenty consecutive trading days immediately preceding the date of prepayment equals or exceeds $40 per share. The notes mature on March 29, 2004 and are payable in cash. The warrants grant the right to purchase one share of common stock at the exercise price of $22.50 for each $50.00 in face value of the convertible notes at any time before March 30, 2004. We expect to register the warrants and underlying common stock for conversion of the debentures, payment of interest and exercise of the warrants.

LIQUIDITY AND OTHER RISK FACTORS

Based upon our current plans, we believe that the convertible debt financing completed subsequent to December 31, 1998, together with existing working capital and future funds from Novartis, including product and royalty revenue, will be sufficient to finance operations into 2000. However, this statement is forward-looking and changes may occur that would significantly decrease available cash before such time. Factors that may change our cash requirements include:

. Time required to obtain regulatory approvals of products in different countries, if needed, and subsequent timing of product launches;
. Commercial acceptance and reimbursement when product launches occur;
. Progress of research and development programs; Resources devoted to outside research collaborations or projects, self-funded projects, proprietary manufacturing methods and advanced technologies; and
. Acquisition of a second manufacturing plant.

Any of these events could adversely impact our capital resources, requiring us to raise additional funds. Additional funds may not be available when required on acceptable terms. If adequate funds are not available when needed, we would need to delay, scale back or eliminate certain research and development programs or license to third parties certain products or technologies that we would otherwise undertake ourselves, resulting in a potential material adverse effect on our financial condition and results of operations.

YEAR 2000

The Year 2000 issue ("Y2K") refers to potential problems with computer systems or any equipment with computer chips or software that use dates where the year has been stored as just two digits (e. g., 98 for 1998). On January 1, 2000, any clock or date recording mechanism incorporating date sensitive software which uses two digits to represent the year may recognize a date using 00 as the year 1900 rather than the year 2000. This could result in a system failure or miscalculations causing disruption of operations, including, among other things, a temporary inability to manufacture product or process transactions, send invoices or engage in similar business activities.

STATE OF READINESS

In order to address this situation, we conducted an assessment to identify and determine the Y2K readiness of our systems. This assessment program focused on three main functional areas, including:

. Information technology which addresses data, phone and administrative systems;
. Embedded chip technology which addresses manufacturing systems, laboratory instruments and plant maintenance systems with programmable logic controllers with date functions; and
. Material suppliers, vendors and other third parties that address areas that are critical to the manufacturing process, distribution of product or other business processes.

The task of assessment from a Y2K readiness perspective is 100% complete. Some of our systems are Y2K compliant, whereas other systems have been identified as not being Y2K compliant and remedial action is underway. Remedial plans have been developed for the remaining software and systems to bring them into Y2K compliance in time to minimize any detrimental effects on operations. In addition to the assessment of systems, key vendors, suppliers and other third parties were identified and a survey form was sent to each of these business entities to determine if their systems are Y2K compliant. We are monitoring responses as they are received. Y2K issues with our vendors, suppliers or other third parties could delay the shipment and receipt of critical supplies, potentially impacting production and operations. We are proactively addressing the Y2K issue with vendors, suppliers and other third parties to minimize risk from these external factors.

COST OF YEAR 2000 COMPLIANCE AND CONTINGENCY PLANS

While our Y2K project is not yet complete, we currently estimate that costs associated with the Y2K issue will be no more than $250,000, which includes the use of internal resources. Working capital will be used to fund these costs. To date, costs consist primarily of payroll costs for existing employees, including the information technology group, which are not separately tracked, as well as certain software upgrade and training costs. However, certain aspects of the Y2K assessment are still ongoing. If we or key third parties such as suppliers and customers are not Y2K ready, there could be an adverse effect on our business, results of operations and financial condition. We believe that with the implementation of the Y2K program the risk of significant interruptions of normal operations is reduced. We are developing a contingency plan to address a situation in which Y2K problems do cause an interruption in normal business activities. Once developed, contingency plans and related cost estimates will be continually refined as additional information becomes available.

ACCOUNTING PRONOUNCEMENTS

In March of 1998, the American Institute of Certified Public Accountants issued Statement of Position 98-1, "Accounting for the Costs of Computer Software Developed or Obtained for Internal Use." SOP 98-1 requires computer software costs associated with internal use software to be charged to operations as incurred until certain capitalization criteria are met. SOP 98-1 is effective beginning January 1, 1999. We do not expect adoption of this statement to have a material effect on consolidated financial position or results of operations.

In June of 1998, the FASB issued SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities." SFAS No. 133 establishes accounting and reporting standards for derivative instruments, including certain derivative instruments embedded in other contracts and for hedging activities. SFAS No. 133 is effective for fiscal years beginning December 15, 1999. We do not expect adoption of this statement to have a material impact on consolidated financial position or results of operations.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

ORGANOGENESIS INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

CONSOLIDATED FINANCIAL STATEMENTS INCLUDED IN ITEM 8:

REPORT OF INDEPENDENT ACCOUNTANTS

To the Board of Directors and Stockholders of Organogenesis Inc.:

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, cash flows, and changes in stockholders' equity present fairly, in all material respects, the financial position of Organogenesis Inc. at December 31, 1998 and 1997, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 1998, in conformity with generally accepted accounting principles. These financial statements are the responsibility of the Company's management; our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with generally accepted auditing standards which require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for the opinion expressed above.

PricewaterhouseCoopers LLP

Boston, Massachusetts
March 30, 1999